

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**NanoRepro AG
Untergasse 8
35037 Marburg
Germany**

for the scope

**rapid test for the detection of antibodies to HIV-1/2 in whole blood, serum or plasma,
and immunochromatographic rapid tests for self-testing
(see attachment)**

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

**Annex IV – excluding Section 4 and 6
of the Council Directive 98/79/EC**

of the European Parliament and of the Council of
27 October 1998 on in vitro diagnostic medical devices.

The surveillance will be held as specified in Annex IV, Section 5.

Valid from	2017-03-06
Valid until	2021-01-25
Registration no.	D1368900016
Report no.	P16-01797-87426
Stuttgart	2017-03-06


Head of Certification Body

